UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/538,864	03/29/2000	Myeong-Je Cho	2001-0703.30	6374

7590 12/13/2001

Michael R. Ward
Morrison & Foerster LLP
425 Market Street
San Francisco, CA 94105-2482

EXAMINER	
EINSMANN, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1655	16

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/538,864	CHO ET AL.	
	Examiner	Art Unit	
	Juliet C Einsmann	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2001 and 01 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-43,77-86 and 112-149* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-43,77-86 and 112-149* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is written in response applicant's correspondence submitted 9/24/01 and 9/28/01, paper numbers 14 and 15. Claims 32, 36, 38, 40, 77, 79, 82, and 83 have been amended, claims 1-31, 44-76, and 87-111 have been canceled, and claims 112-149 have been added. Claims 32-43, 77-86, and 112-149 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Although one hyperlink on page 14 was deleted, there are others in the specification, including, for example, page 8 line 31 and page 14, line 29.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 32-43, 77-86, and 112-149 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to monocot transgenic plants and seeds which comprise a promoter active in said plant operably linked to a nucleic acid encoding a monocot thioredoxin polypeptide. In order to be in possession of such plants, at the very least applicants must be in possession of nucleic acids encoding the appropriate monocot thioredoxin polypeptides. The prior art provides only three nucleic acids encoding monocot thioredoxins, two thioredoxin h cDNAs from wheat (Gautier *et al.* 1998) and one thioredoxin h cDNA from rice (Ishiwatari *et al.* 1995). The instant specification, in example 6 provide a nucleic acid which encodes a barley thioredoxin h (SEQ ID NO: 24). There are thousands of possible moncots, and each of these would express multiple types of thioredoxins. Thus, of all of the thousands of possible nucleic acids encoding all of the different types thioredoxins in monocot plants, applicant is in express possession of only four nucleic acids encoding monocot thioredoxin h polypeptides. Neither Applicant nor the prior art provide any other thioredoxin molecules from other monocots. Specifically, both Applicant and the prior art are silent as to the nucleic acid sequences which encode any maize, oat, rye, sorghum, millet, triticale, turf grass, or forage grass thioredoxin polypeptides, yet plants specifically comprising each of these are claimed. Furthermore, Applicant is not in possession of any wheat, barley or rice thioredoxin molecules other than those that have been specifically disclosed as discussed above. Neither Applicant nor the prior art provide any nucleic acid encoding thioredoxin polypeptides from moncots that encode other types thioredoxin molecules besides thioredoxin h polypeptides.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of transgenic plants comprising any and all possible nucleic acids encoding monocot thioredoxin molecules which has nucleic acids modified by addition, insertion, deletion, substitution or inversion with the molecules disclosed by Ishiwatari *et al.*, Gautier *et al.* or herein in example 6 but retaining correlative function in the claimed products.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 78, 82, 83, 84, 85, 112, 113, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 133, 134, 136, 138, 140, 142, 144, 146, and 148 rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez (US 5889189) in view of

Ishiwatari *et al.* (Planta, 1995, 195(3)456-463), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662).

Rodriguez teaches transgenic monocot plants which express genes of interest (ABSTRACT). Rodriguez teaches that the method is useful for the production of any polypeptide of interest, including enzymes and industrial proteins (Col. 11, lines 34-47). Rodriguez teaches that the methods for producing polypeptides of interest utilize edible varieties of grasses, including, for example, wheat, rice, barley, corn, oats, and millet (Col. 9, lines 45-50). Rodriguez specifically teaches the production of seeds from said monocot plants, further teaching the use of seed specific promoters (Col. 13, lines 42-44) and signal sequences which target the endosperm (Col. 12, lines 30-37).

Rodriguez does not teach transgenic plants expressing thioredoxins.

Ishiwatari *et al.* teach the cDNA encoding a thioredoxin h polypeptide from the monocot rice (Fig. 3). Further, Ishiwatari *et al.* teach methods in which the polypeptide was over expressed in E. coli (p. 457).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced transgenic plants producing a monocot thioredoxin such as the one taught by Ishiwatari *et al.* using any of the routine methods taught by Rodriguez. The ordinary practitioner would have been motivated by the successful expression of thioredoxins in E. coli by Ishiwatari *et al*, by a desire to produce industrially useful thioredoxin polypeptide, and by the teachings the use transgenic plants for the production of industrial enzymes as taught by Rodriguez. Thioredoxins were widely known at the time the invention was made to be enzymes with many industrial uses, including in the flour making industry, as is admitted by the instant

specification, and Rodriguez specifically teaches the advantages of such a method for the production of polypeptides stating "The compositions and methods described herein allow low-cost, high-volume eukaryotic production of selected gene products, such as, proteins and polypeptides, based on the malting of transgenic seeds (Col. 9, lines 9-13)." In the absence of a secondary consideration, such as an unexpected result, the instantly broadly claimed invention is free of the prior art. With regard to the claims specifically drawn to triticale and sorghum transgenic plants, at the time the invention was made, the selection of one of any number of plant species to be transformed for the expression of industrial enzymes would have been routine, a matter solely of experimental design. The ordinary practitioner would have recognized that the teachings of Rodriguez encompass the production of transgenic plants in any number of monocots and edible grains as discussed above. Triticale and sorghum are such a plants, and thus the transformation of triticale or sorghum is considered to be encompassed by the teachings of Rodriguez.

While the examiner believes that adequate motivate to make the claimed invention is provided by the above rejection, Shi *et al.* provide further motivation to make transgenic plants that produce thioredoxin h. Shi *et al.* experiments in which they transformed tobacco plants with thioredoxin h for the purpose of studying thioredoxin h activity in plants (p. 654 and 657). Shi *et al.* further teach that thioredoxins are active in many biochemical processes in plants (p. 654). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Thus, the combined teachings of Rodriguez, Ishiwatari *et al.* and Shi *et al.* would have further motivated the production of monocot plants expressing transgenic monocot thioredoxin h molecules. The teachings of Ishiwatari *et al.* provide a

monocot thioredoxin of interest, the teachings of Rodriguez specifically provide methodology for the transformation of monocots, and Shi *et al.* demonstrate that the production of transgenic plants producing thioredoxin h is of interest in elucidating the functionality of thioredoxin h in plants. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made transgenic plants expressing these thioredoxin h molecules. The ordinary practitioner would have been motivated to transform transgenic plants with these molecules in order to further study the biological function of the thioredoxin h polypeptides plants, or as an alternative method for producing thioredoxin h polypeptides for study. The ordinary practitioner would have been motivated by the success of Shi *et al.*'s expression of thioredoxin to extend this method to the thioredoxin molecules taught by Ishiwatari *et al.* The ordinary practitioner would have also been motivated by the teachings of Rodriguez to produce specifically monocot plants producing thioredoxin h in order to study the activity of this polypeptide in monocot plants.

Thus for all of these reasons, the rejected claims are prima facie obvious in view of the prior art.

7. Claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 78, 82, 83, 84, 85, 112, 114, 116, 119, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 139, 140, 142, 144, 146, and 148 rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez (US 5889189) in view of Gautier *et al.* (1998, European Journal of Biochemistry, 252:314-324), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662).

Rodriguez teaches transgenic monocot plants which express genes of interest (ABSTRACT). Rodriguez teaches that the method is useful for the production of any

polypeptide of interest, including enzymes and industrial proteins (Col. 11, lines 34-47). Rodriguez teaches that the methods for producing polypeptides of interest utilize edible varieties of grasses, including, for example, wheat, rice, barley, corn, oats, and millet (Col. 9, lines 45-50). Rodriguez specifically teaches the production of seeds from said monocot plants, further teaching the use of seed specific promoters (Col. 13, lines 42-44) and signal sequences which target the endosperm (Col. 12, lines 30-37).

Rodriguez does not teach transgenic plants expressing thioredoxins.

Gautier *et al.* teach the cDNA encoding a thioredoxin h polypeptide from the monocot wheat (Fig. 1). Further, Gautier *et al.* teach methods in which the polypeptide was over expressed in E. coli (p. 317-318).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced transgenic plants producing a monocot thioredoxin such as the one taught by Gautier *et al.* using any of the routine methods taught by Rodriguez. The ordinary practitioner would have been motivated by the successful expression of thioredoxins in E. coli by Gautier *et al*, by a desire to produce industrially useful thioredoxin polypeptide, and by the teachings the use transgenic plants for the production of industrial enzymes as taught by Rodriguez. Thioredoxins were widely known at the time the invention was made to be enzymes with many industrial uses, including in the flour making industry, as is admitted by the instant specification, and Rodriguez specifically teaches the advantages of such a method for the production of polypeptides stating "The compositions and methods described herein allow low-cost, high-volume eukaryotic production of selected gene products, such as, proteins and polypeptides, based on the malting of transgenic seeds (Col. 9, lines 9-13)." In the absence of a

secondary consideration, such as an unexpected result, the instantly broadly claimed invention is free of the prior art. With regard to the claims specifically drawn to triticale and sorghum transgenic plants, at the time the invention was made, the selection of one of any number of plant species to be transformed for the expression of industrial enzymes would have been routine, a matter solely of experimental design. The ordinary practitioner would have recognized that the teachings of Rodriguez encompass the production of transgenic plants in any number of monocots and edible grains as discussed above. Triticale and sorghum are such a plants, and thus the transformation of triticale or sorghum is considered to be encompassed by the teachings of Rodriguez.

While the examiner believes that adequate motivate to make the claimed invention is provided by the above rejection, Shi *et al.* provide further motivation to make transgenic plants that produce thioredoxin h. Shi *et al.* experiments in which they transformed tobacco plants with thioredoxin h for the purpose of studying thioredoxin h activity in plants (p. 654 and 657). Shi *et al.* further teach that thioredoxins are active in many biochemical processes in plants (p. 654). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Thus, the combined teachings of Rodriguez, Gautier *et al.* and Shi *et al.* would have further motivated the production of monocot plants expressing transgenic monocot thioredoxin h molecules. The teachings of Gautier *et al.* provide a monocot thioredoxin of interest, the teachings of Rodriguez specifically provide methodology for the transformation of monocots, and Shi *et al.* demonstrate that the production of transgenic plants producing thioredoxin h is of interest in elucidating the functionality of thioredoxin h in plants. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention

was made to have made transgenic plants expressing these thioredoxin h molecules. The ordinary practitioner would have been motivated to transform transgenic plants with these molecules in order to further study the biological function of the thioredoxin h polypeptides plants, or as an alternative method for producing thioredoxin h polypeptides for study. The ordinary practitioner would have been motivated by the success of Shi *et al.*'s expression of thioredoxin to extend this method to the thioredoxin molecules taught by Gautier *et al.* The ordinary practitioner would have also been motivated by the teachings of Rodriguez to produce specifically monocot plants producing thioredoxin h in order to study the activity of this polypeptide in monocot plants.

Thus for all of these reasons, the rejected claims are prima facie obvious in view of the prior art.

8. Claims 36-37, 43, 79-81 and 86 rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez (US 5889189) in view of Ishiwatari *et al.* (Planta, 1995, 195(3)456-463), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 78, 82, 83, 84, 85, 112, 113, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 133, 134, 136, 138, 140, 142, 144, 146, and 148 above, and further in view of Cho *et al.* (In vitro Cellular and Developmental biology 34(3) part 2 (March 1998) p. 48A) OR as being unpatentable over Rodriguez (US 5889189) in view of Gautier *et al.* (1998, European Journal of Biochemistry, 252:314-324), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 78, 82, 83, 84, 85, 112, 114, 116, 119, 120, 122,

124, 126, 128, 130, 132, 134, 136, 138, 139, 140, 142, 144, 146, and 148 above and further in view of Cho *et al.* (In vitro Cellular and Developmental biology 34(3) part 2 (March 1998) p. 48A).

The teachings of Rodriguez (US 5889189) in view of Ishiwatari *et al.* (Planta, 1995, 195(3)456-463), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) and the teachings of Rodriguez (US 5889189) in view of Gautier *et al.* (1998, European Journal of Biochemistry, 252:314-324), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) are applied to this rejection as discussed above. None of these previously cited references teach the use of a barley B1 Hordein promoter or signal peptide. However, Rodriguez does specifically teach that the "also included in chimeric gene used in the practice of the method of the present invention are signal secretion sequences (Col. 12, lines 15-17)," and that "those of skill can routinely identify new signal peptides (Col. 13, line 19), and that "the preferred transcription regulatory or promoter region is chosen so as to be relatively silent, except during seed germination (Col. 13, lines 42-44). Thus, Rodriguez teaches that alternative signal and regulatory sequences can be used with their invention.

Cho *et al.* teach the barley B_1-hordein regulatory regions and signals that direct sub-cellular localization of proteins in the endosperm. They teach that stronger activity was detected when the transformed endosperm tissue contained the signal sequence that without the signal sequence. Further they teach that the gene driven by the B_1-hordein regulatory elements was stabley inherited and expressed in T_2 progeny.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the regulatory sequences and signal sequence taught by Cho *et al.* to produce transgenic plants as taught by Rodriguez) in view of Ishiwatari *et al.*, and optionally, both of these further in view of Shi *et al.* or to product transgenic plants as taught by Rodriguez in view of Gautier *et al.*, and optionally, both of these further in view of Shi *et al.* The ordinary practitioner would have been motivated by the teachings of Cho *et al.* that the barley B1-hordein regulatory element coupled with the signal sequence drive endosperm specific expression and by the teachings of Rodriguez that other regulatory sequences can be used in to produce transgenic plants according to their invention.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 78, 82, 83, 84, 85, 112, 114, 115, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 135, 136, 138, 140, 142, 144, 146, and 148 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 9, 10, 12, 15, 16, 17, 18, 63, 64, 72, 74, 75, and 76 of copending Application No. 09/540014 in view of Rodriguez.

The claims in the '014 patent are drawn to transgenic plants and seeds comprising a barley thioredoxin h that is identical to instant SEQ ID NO: 24. The claims of the '014 patent do not specifically indicate the species of the plants. However, the species of plant in which the barley thioredoxin h is expressed is merely a matter of experimental choice. Methods for the expression of polypeptides in monocots were routine in the art at the time the invention was made. For example, Rodriguez teaches transgenic monocot plants which express genes of interest (ABSTRACT). Rodriguez teaches that the method is useful for the production of any polypeptide of interest, including enzymes and industrial proteins (Col. 11, lines 34-47). Rodriguez teaches that the methods for producing polypeptides of interest utilize edible varieties of grasses, including, for example, wheat, rice, barley, corn, oats, and millet (Col. 9, lines 45-50). Rodriguez specifically teaches the production of seeds from said monocot plants, further teaching the use of seed specific promoters (Col. 13, lines 42-44) and signal sequences which target the endosperm (Col. 12, lines 30-37).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced transgenic monocot plants producing the barley thioredoxin h recited in the claims of the '014 application using any of the routine methods taught by Rodriguez. The ordinary practitioner would have been motivated by a desire to produce industrially useful thioredoxin polypeptide, and by the teachings the use transgenic plants for the production of industrial enzymes as taught by Rodriguez. Thioredoxins were widely known at the time the invention was made to be enzymes with many industrial uses, including in the flour making industry, as is admitted by the instant specification, and Rodriguez specifically teaches the advantages of such a method for the production of polypeptides stating

"The compositions and methods described herein allow low-cost, high-volume eukaryotic production of selected gene products, such as, proteins and polypeptides, based on the malting of transgenic seeds (Col. 9, lines 9-13)." In the absence of a secondary consideration, such as an unexpected result, the instantly broadly claimed invention is free of the prior art. With regard to the claims specifically drawn to triticale and sorghum transgenic plants, at the time the invention was made, the selection of one of any number of plant species to be transformed for the expression of industrial enzymes would have been routine, a matter solely of experimental design. The ordinary practitioner would have recognized that the teachings of Rodriguez encompass the production of transgenic plants in any number of monocots and edible grains as discussed above. Triticale and sorghum are such a plants, and thus the transformation of triticale or sorghum is considered to be encompassed by the teachings of Rodriguez.

This is a provisional obviousness-type double patenting rejection.

11. Claims 36-37, 43, 79-81 and 86 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 9, 10, 12, 15, 16, 17, 18, 63, 64, 72, 74, 75, 76 of copending Application No. 09/540014 in view of Rodriguez, as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 78, 82, 83, 84, 85, 112, 114, 115, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 135, 136, 138, 140, 142, 144, 146, and 148 above, and further in view of Cho *et al.* (In vitro Cellular and Developmental biology 34(3) part 2 (March 1998) p. 48A).

Neither the claims of the '014 patent nor Rodriguez teach the use of a barley B1 Hordein promoter or signal peptide. However, Rodriguez does specifically teach that the "also included in chimeric gene used in the practice of the method of the present invention are signal secretion

sequences (Col. 12, lines 15-17)," and that "those of skill can routinely identify new signal peptides (Col. 13, line 19), and that "the preferred transcription regulatory or promoter region is chosen so as to be relatively silent, except during seed germination (Col. 13, lines 42-44). Thus, Rodriguez teaches that alternative signal and regulatory sequences can be used with their invention.

Cho *et al.* teach the barley B_1-hordein regulatory regions and signals that direct sub-cellular localization of proteins in the endosperm. They teach that stronger activity was detected when the transformed endosperm tissue contained the signal sequence that without the signal sequence. Further they teach that the gene driven by the B_1-hordein regulatory elements was stabley inherited and expressed in T_2 progeny.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the regulatory sequences and signal sequence taught by Cho *et al.* to produce transgenic plants as taught by the co-pending claims in view of Rodriguez . The ordinary practitioner would have been motivated by the teachings of Cho *et al.* that the barley B1-hordein regulatory element coupled with the signal sequence drive endosperm specific expression and by the teachings of Rodriguez that other regulatory sequences can be used in to produce transgenic plants according to their invention.

This is a provisional obviousness-type double patenting rejection.

Claim 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 78, 82, 83, 84, 85, 112, 114, 115, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 135, 136, 138, 140, 142, 144, 146, and 148 and claims 36-37, 43, 79-81 and 86 are directed to an invention not patentably distinct from claim 8, 9, 10,

12, 15, 16, 17, 18, 63, 64, 72, 74, 75, and 76 of commonly assigned 09/540014, as discussed in the double patenting rejections above. These two applications have different inventive entities.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/540014, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Response to Remarks

Many of applicant's remarks are addressed by the new grounds of rejection provided above. Specifically, Rodriguez provides clear direction as to the use of transgenic monocots for the production of enzymes in plants. Monocot thioredoxin h molecules are provided by Ishiwatari *et al.* and Gautier *et al.*

Applicant asserts that the unexpected results provided herein fully support the amended claims which are now directed to transgenic monocots expressing monocot thioredoxin. the examiner disagrees. The only unexpected results provided in the specification are with regard to barley plants expressing thioredoxin h and wheat plants expressing both thioredoxin h and Arabidopsis NTR.

With regard to barley plants expressing wheat thioredoxin h, the specification demonstrates that seeds produced from these plants have increased activity of α-amylase and pullulanase. Further, it was demonstrated that seeds from these plants germinate earlier than seeds from transgenic plants lacking the transgene.

With regard to wheat plants over-expressing wheat thioredoxin h and Arabidopsis NTR, the specification provides unexpected results with regard to increased digestibility and reduced allergenicity in these plants.

The MPEP states that "the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range (MPEP 716.02(d))." With regard to monocot plants expressing monocot thioredoxin, the unexpected results have only been provided with regard to wheat thioredoxin h in barley. With regard to wheat plants expressing both thioredoxin h and Arabidopsis NTR, this result is not sufficient to extend the breadth of the range of the unexpected results because it is not clear if it is the thioredoxin h or the NTR or a combination of the two that is causative of the resulting phenotype. There is no showing of an unexpected result for the use of any other thioredoxin besides wheat thioredoxin h, and there is no showing of unexpected results for plants transformed with wheat thioredoxin h besides barley plants. Thus, the instantly claimed invention is outside of the scope of the demonstrated unexpected results.

Claims which are drawn to be commensurate in scope with these unexpected results would not be considered obvious over the prior art. For example, a transgenic barley plant wherein at least part of said plant comprises a recombinant nucleic acid comprising a promoter active in said part operably linked to a nucleic acid molecule encoding a wheat thioredoxin h polypeptide, would be allowable.

Applicant points out that Example 6 describes transgenic sorghum plants expressing barley thioredoxin h, suggesting that these plants help to expand the scope of the demonstrated unexpected results. However, with regard to the transgenic sorghum plants, the teachings of Example 6 are prophetic. No data is provided concerning the phenotypic characteristics of this plant, and thus there is no evidence of any result, let alone an unexpected result. However, transgenic plants expressing SEQ ID NO: 24 would be free of the art and fully described because the instant specification provides SEQ ID NO: 24 for the first time. Applicant is reminded, however, that the '014 patent described above contains claims drawn to this subject matter.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1655

December 7, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600